IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

RETRACTABLE TECHNOLOGIES, INC. Plaintiff, v. OCCUPATIONAL & MEDICAL INNOVATIONS, LTD. Defendant	§ § § § § § § § § §	Civil Action No. 6:08-cv-120 **Jury Trial Demanded**

COMPLAINT

Plaintiff Retractable Technologies, Inc. ("Retractable") files this Complaint for patent infringement and related causes of action against Defendant Occupational & Medical Innovations, Ltd. ("OMI"), in support of which Retractable alleges as follows.

I. THE PARTIES

1. Retractable is a Texas corporation having a principal place of business in Little Elm, Collin County, Texas.
2. OMI is an Australian corporation having a principal place of business at Unit 1/12 Booran Drive, Slacks Creek, Queensland 4127, Australia, and having a sales agent, TriAxis Medical Solutions, with a principal place of business at 4197 Honor Drive, Frisco, Collin County, Texas.

II. JURISDICTION AND VENUE

3. The Court has general jurisdiction and specific personal jurisdiction over OMI based upon the facts and acts described below, including but not limited to the acts discussed in paragraphs 19-25. OMI is engaged in business in Texas and this lawsuit arises out of its

business contacts in Texas. It does not maintain a regular place of business in Texas and is not required by statute to designate or maintain a registered agent for service of process in Texas. OMI may be served with process through the Secretary of State under the Texas Long Arm Statute, Tex. Civ. Prac. & Rem. Code §17.041, et seq. This Court has personal jurisdiction over OMI under the Texas Long Arm Statute because it is doing business within Texas within the meaning of that statute.

4. The Court has subject matter jurisdiction under at least the following: 15 U.S.C. 1125(a); 28 U.S.C. §§1331, 1332(a)(2), 1338 and 1367, and 35 U.S.C. §281.

5. The amount in controversy is over $75,000.

6. Venue in this federal judicial district is proper under at least the following: 28 U.S.C. §§1400(b) and 1391(d).

III. INTRODUCTION

7. Retractable brings this action against OMI because OMI is now selling in the United States safety syringes that infringe Retractable's United States Patents and that are being manufactured in China by the same business entity that manufactures syringes for Retractable. In addition to patent infringement, OMI has illegally competed with Retractable through theft of confidential information, intentional interference with contracts and by engaging in false advertising that wrongfully disparages and mischaracterizes Retractable's products and makes false allegations regarding the source of origin of OMI's safety syringe products that are now being offered for sale in the United States.

IV. FACTUAL BACKGROUND

Retractable's Patented Safety Syringes

8. Retractable is a small, publicly owned Texas company manufacturing a revolutionary safer alternative to traditional needles and syringes. In the early 1990s, founder Thomas Shaw developed and patented a new safety syringe that is marketed by Retractable under the name "VanishPoint®." Development of the new safety syringe was initially funded by two Small Business Innovation Research ("SBIR") grants received from the National Institute on Drug Abuse, a division of the National Institutes of Health ("NIH"). The VanishPoint® syringe offers reliable protection against the spread of potentially deadly blood-borne pathogens due to syringe reuse or due to accidental needle-stick injuries, and does not require the user to take any additional steps to render the syringe safe. The VanishPoint® syringe automatically retracts the needle back inside the syringe body when the plunger is fully depressed after it has delivered medicine into a patient. There is virtually no chance for a nurse or doctor to be accidentally stuck by a needle that has been in contact with a patient's blood as the needle is no longer exposed after an injection has been given. Because the nurse or doctor only needs to push the syringe plunger completely to retract the needle, the VanishPoint® is designed to require no separate action to retract the needle. When the syringe is used as designed, the needle will retract as the nurse or doctor finishes injecting medicine into the patient. This is referred to as a passive safety device as opposed to an active device that requires the user to take affirmative action to engage it. Retractable also manufactures retracting safety insulin syringes, retracting safety blood collection devices, and safety intravenous catheters.

9. Retractable's VanishPoint® syringes are manufactured in plants located in Little Elm, Texas and in China, and are being offered for sale in countries throughout the world. Retractable's

products are made in China by Double Dove Group Co. Ltd. ("Double Dove"), an entity that was under a contract (hereinafter "Manufacturing Agreement") prohibiting Double Dove from manufacturing retractable syringes for any party other than Retractable and from using or disclosing information developed with respect to Retractable's syringes other than for the manufacture of Retractable's VanishPoint® syringes. Retractable disclosed its valuable confidential information and trade secrets to Double Dove under confidentiality provisions that remain in effect in order to enable Double Dove to manufacture the VanishPoint® syringes. Retractable's confidential information and trade secrets cannot be easily and properly acquired or duplicated by others.

10. Clinical acceptance of the VanishPoint® syringes has been demonstrated by the placement of approximately four million units in U.S. governmental facilities and almost 500 million units in the global marketplace. Retractable is the only U.S. manufacturer of syringes that has supplied retractable syringes for use in the President's $15 billion AIDS relief program for African nations**.** The new safety syringe and Retractable have been featured in major news publications and on CBS' *60 Minutes.*

11. In 2003, Frost & Sullivan, an international business research and consulting firm, named Retractable as the recipient of its Product Quality Leadership Award for developing, manufacturing and marketing the VanishPoint® line of automated retraction safety needle devices. Frost & Sullivan found that the VanishPoint® product line represented a major improvement over other retractable syringes then on the market. Amit Bohora, a Frost & Sullivan industry analyst, stated, "VanishPoint® devices are clearly the gold standard in retractable syringes." Retractable has been recognized as a superior safety product by

independent rating agencies, studies and scholarly reviews, and polls and questionnaires of nurses and doctors.

OMI Illegally Gains Access to Retractable's Confidential Information

12. Retractable's confidential information was generated by Double Dove with respect to Retractable's VanishPoint® retractable syringes under the Manufacturing Agreement. This includes various testing and analysis that is required by the FDA in order to allow a syringe product to be marketed in the United States. Pursuant to the Manufacturing Agreement, this information is highly sensitive and is considered Retractable's confidential information. This additional Retractable confidential information is not generally known outside of Retractable and Double Dove. Because this information has great value to Retractable, significant measures are taken by Retractable and are required to be taken by Double Dove to ensure that this information remains confidential. This information is the result of substantial time, effort and expense by and/or on behalf of Retractable and gives Retractable a substantial business advantage over other competitors who do not know or use it.
13. OMI entered into an agreement with China Medical Group, a subsidiary of Double Dove, in October of 2003 to manufacture retractable syringes for OMI.
14. On information and belief, OMI was aware of the restrictions on Double Dove as a result of Double Dove's Manufacturing Agreement with Retractable and the prohibition against Double Dove's contracting with OMI. Nevertheless, OMI received Retractable's confidential information.
15. Upon information and belief, OMI was aware that it was receiving Retractable confidential information in breach of the Manufacturing Agreement between Retractable and Double Dove.

16. On information and belief, at the time it contracted with Double Dove, through China Medical Group, Defendant OMI had its own retractable syringe design. However, that design could not be manufactured at significant volumes. From 2004 through 2006, OMI periodically reported to the Australian Stock Exchange that it was still having problems manufacturing syringes in commercial quantities. OMI even admitted in its 2004 annual chairman's address that "[T]he idea of a research and development company with less than 20 employees (few, if any with process manufacturing experience), attempting to take three complex products into mass manufacture in a foreign Country is simply overly ambitious." OMI did not have a retractable syringe on the market until some time in 2007.
17. On information and belief, Double Dove, using Retractable's confidential information and trade secrets, assisted Defendant OMI in redesigning its retractable syringes during this period so that they worked and could be manufactured in significant volumes.
18. On information and belief, the current OMI retractable syringes incorporate and are the result of the wrongful use of Retractable confidential information by OMI. On August 13, 2007 OMI announced that it had demonstrated its retractable syringes for a potential distributor in the United States.
19. On March 6, 2008, OMI announced publicly that OMI had appointed Cardinal Health as a North American distributor, that the guaranteed minimum order quantities under the distributorship agreement will approximate USD $4.3 million in calendar 2008, that approximately 25% of the revenue is anticipated to be booked by March 31, 2008, that all production tooling has been validated and large quantity production runs have been successfully completed during Cardinal Health's auditing process (with quality meeting all FDA validation and regulatory requirements), that the syringes are packaged and branded

with the Cardinal Health logo, that meticulous and conclusive design and regulatory approvals to complete the artwork and packaging for the Cardinal Health Private Label for the OMI syringe has been finalized and signed off, that the required "Certificate of Completion of Supplier Audit" has been received from Cardinal Health's Shanghai office, that syringe manufacture is in full production and completion of Cardinal Health's initial stocking order ("ISO") is expected by the end of March 2008 with additional orders expected soon thereafter, that delivery of the ISO as each run passes OMI's batch testing has begun and the first shipments of the ISO have been received into Cardinal Health's U.S. warehouse, with revenue booked accordingly, that OMI anticipates approximately USD $1 million of the committed calendar 2008 orders will be booked by March 31, 2008, that OMI anticipates receipting cash flow from these sales in March 2008, that OMI confirms its earlier advice that syringe sales into North America under the Cardinal Health distribution agreement will increase top line revenue by a minimum of USD $4.3 million in calendar 2008, and that more than 50% of the revenue increase will be booked by June 30, 2008.

20. On Thursday, March 27, 2008, Kevin Kohler, Regional Sales Manager for Retractable, was present at and made a presentation at a meeting held in Austin, Texas at the Texas Department of State Health Services ("DSHS") for the purpose of promoting continued sales of Retractable's products, including VanishPoint® syringes having retractable needles, to that state agency. Retractable has been selling VanishPoint® retractable syringes and other products to DSHS for a number of years, and currently sells to DSHS through McKesson, another national distributor of medical products. On information and belief, DSHS holds this meeting annually for the purpose of reviewing medical products currently being purchased by, or being offered for sale to, the agency. Products purchased by the agency are shipped

initially to its distribution facility in Austin and then redistributed by the agency to its various field offices throughout the state.

21. Also present at the March 27, 2008 meeting in Austin, Texas, and making a presentation to the agency were Fred Kratz, President of TriAxis Medical Solutions, of Frisco, Collin County, Texas, representing OMI, and Rhonda Conklin, Sales Representative for Physician Products and Services for Cardinal Health, who offices in San Antonio, Texas.

22. While waiting to begin his presentation, Mr. Kohler began conversing with Mr. Kratz and Ms. Conklin, who showed him a new syringe product that they were offering for sale to the agency at the meeting. Mr. Kohler was permitted to handle one of the syringes, open the package, inspect and activate the syringe. The syringe had a retractable needle and was identified with markings for Cardinal Health. Mr. Kohler asked for and received business cards from Mr. Kratz and Ms. Conklin.

23. On information and belief, the OMI/Cardinal syringe Mr. Kohler examined is one of the syringes having retractable needles that have recently been touted by OMI as being the syringes currently being shipped from OMI's Chinese manufacturer (related to Double Dove) to the U.S. for distribution through Cardinal Health.

24. On information and belief, OMI, through its distributors, sales representatives and/or agents Cardinal Health and TriAxis Medical solutions, offered its syringes having retractable needles for sale in the State of Texas and to the Texas Department of State Health Services in Austin, Texas, at least as early as March 27, 2008.

OMI Engages in False Advertising

25. In November 2007, OMI displayed its retractable syringe products and accompanying sales literature to attendees at an international trade show, *Medica 2007*, held in Dusseldorf, Germany. This trade show was attended by consumers of such medical products in the

United States. On information and belief, OMI distributed at the tradeshow and has otherwise distributed to customers and prospective customers for its retractable syringes in the United States a brochure titled "*OMI Safety Syringe.*" A copy of the brochure is attached as Exhibit C to this Complaint.

26. The brochure "*OMI Safety Syringe*" directs the reader's attention to the "KEY BENEFITS" section of the brochure and to the accompanying graph titled "Waste Space Comparison – 3mL Syringe." The brochure purportedly compares the waste space volume ("WSV") of OMI's Safety Syringe to that of the VanishPoint® syringe as currently marketed by Retractable. The graph shows the WSV of the OMI syringe to be 0.016 mL and the WSV of the VanishPoint® syringe to be 0.143 mL. The graph further states: "Source: University test results. December 2006 document #0791."

27. Contrary to the statements made in the "*OMI Safety Syringe*" brochure, the VanishPoint® syringes marketed by Retractable for more than the past five (5) years have had a WSV that is significantly lower than that stated in the brochure, that complies with ISO standards, and that is directly comparable to the WSV stated for the OMI safety syringe.

28. In December 2007, through legal counsel, Retractable requested by letter from OMI a complete copy of the December 2006 university test results mentioned in the "*OMI Safety Syringe*" brochure and any related report (including but not limited to document #0791), identification of the name and location of the university that performed the test, identification of each principal investigator who supervised the subject test, identification of each person who contributed to or prepared the report, and identification of the source (other than Retractable) of the particular VanishPoint® syringes that were tested. Despite the written

request, OMI failed to provide Retractable with any explanation and refused to provide any such information to Retractable.

29. On information and belief, OMI received a 2004 Australian Design Award for a syringe having a retractable needle. On information and belief, the OMI syringe that won the 2004 Australian Design Award was never manufactured and sold commercially anywhere in the world. However, OMI has repeatedly and persistently maintained that the safety syringes it is now marketing in the United States received that award. On information and belief, such representations have been made on OMI's website, in public releases of information on behalf of OMI in promoting its business and the sale of its stock, and in promoting sales of its safety syringe products to customers in the United States.

30. On information and belief, many of the significant structural features and much of the technology embodied in the safety syringes now being offered for sale by OMI in the United States were in fact invented or designed by Retractable and by Retractable's Chinese manufacturer under a contract that vested ownership of such features and technology in Retractable.

V. RETRACTABLE'S ASSERTED UNITED STATES PATENTS

31. Retractable is the owner of all right, title and interest in and to United States Patent No. 6,572,584 B1 ("the '584 patent"), titled Retractable Syringe With Reduced Retraction Force, issued June 3, 2003. All maintenance fees due for this patent have been paid. No right or license under this patent has previously been granted to OMI. A copy of the '584 patent is attached as Exhibit A to this Complaint.

32. Retractable is the exclusive licensee from Thomas J. Shaw, the sole inventor, of United States Patent No. 7,351,224 B1 ("the '224 patent"), titled Retractable Syringe Assembly

Designed For One Use, issued April 1, 2008, and has the right to sue infringers in its own name. No right or license under this patent has previously been granted to OMI. The '584 and '224 patents have not been invalidated or found to be unenforceable in any prior litigation. A copy of the '224 patent is attached as Exhibit B to this Complaint.

33. The '224 patent is a continuing application claiming priority from United States Patent Nos. 5,578,011, 5,632,733, and 6,090,077, all of which are also exclusively licensed by Retractable. U.S. 5,578,011 (the '011 patent) and 6,090,077 (the '077 patent) have both previously been asserted by Retractable against another defendant and contain claims that have previously been construed pursuant to a Markman proceeding before this Court.

34. At all times relevant to this action, Retractable has marked the packages of its VanishPoint® retractable syringes with the number of the '584 patent as provided by 35 U.S.C. §287 and has complied with the notice provisions of 35 U.S.C. §287 with respect to the '224 patent.

VI. CAUSES OF ACTION

Count I – Patent Infringement

35. Retractable hereby realleges and incorporates by reference into this Count 1 the subject matter of paragraphs 1-34 of this Complaint.

36. OMI is, without permission from Retractable or Thomas J. Shaw, making, having made and importing syringes that infringe at least one claim of each of the '584 and '224 patents ("infringing syringes") into the United States, and is offering for sale and/or selling the infringing syringes in the United States and in the State of Texas, and deriving revenue therefrom in contravention of Retractable's legal and equitable rights and in violation of the patent laws of the United States as set forth in Title 35 of the United States Code, including without limitation, 35 U.S.C. §§271.

37. On information and belief, the activities of OMI as set forth above are also inducing others to infringe the '584 and '224 patents by using the subject syringes, and/or contributing to the infringement of the '584 and '224 patents in the United States during the term of the patents.

38. The infringing activities of OMI have caused damage and irreparable injury to Retractable and, unless enjoined by this Court as provided by 35 U.S.C. § 283, will continue to cause damage to Retractable, for which damages Retractable is entitled to recovery pursuant to 35 U.S.C. §284.

39. On information and belief, at least as to the '584 patent, OMI's infringement of the '584 patent has been willful, intentional, and in deliberate disregard of Retractable's patent rights, and is totally without justification, thereby supporting the award of enhanced damages in an amount equal to three times the amount found or assessed pursuant to 35 U.S.C. §284, and the finding of an exceptional case supporting the award of attorney fees to Retractable under 35 U.S.C. § 285.

Count II – Misappropriation of Trade Secrets and Confidential Information

40. The preceding paragraphs of this Complaint are incorporated herein by reference as if fully set forth.

41. Defendant OMI improperly solicited and obtained Retractable confidential information from Double Dove. Such information was used by Defendant OMI and Double Dove or its affiliates in the development and design of the OMI retractable syringe.

42. Until now, Retractable has not been able to establish personal jurisdiction over OMI in the State of Texas.

43. Defendant's use and disclosure of the confidential information and trade secrets belonging to Retractable constitutes misappropriation and theft of trade secrets, and Defendant has thereby

violated the statutory and common law of the State of Texas. Accordingly, Defendant is liable to Retractable for all of Retractable's actual damages, which are in an amount far in excess of the minimum jurisdictional limits of this Court, resulting from this wrongful misappropriation and theft, together with additional damages as allowed under the law. Defendant's continued use of the improperly obtained Retractable confidential information and trade secrets will cause irreparable injury to Retractable and thus should be preliminarily and permanently enjoined.

Count III -- Conversion

44. The preceding paragraphs of this Complaint are incorporated herein by reference as if fully set forth.

45. The confidential information regarding Retractable's VanishPoint® retractable syringes is the rightful property of Retractable. By wrongfully controlling, disclosing, and utilizing the confidential information of Retractable for its own benefit and the benefit of third parties, Defendant has unlawfully converted Retractable's property in violation of the statutory and common law of the State of Texas.

46. As a direct result of Defendant's conversion, Retractable has been damaged in an amount in excess of the minimum jurisdictional limits of this Court. Defendant's continued use of the converted Retractable confidential information and trade secrets will cause irreparable injury to Retractable and thus should be preliminarily and permanently enjoined.

Count IV — Intentional Interference with Contractual Relations

47. The preceding paragraphs of this Complaint are incorporated herein by reference as if fully set forth.

48. Defendant OMI knowingly interfered with Retractable's contractual relations with Double Dove by inducing Double Dove to breach its contract with Retractable by disclosing Retractable confidential information to one or more third parties, by using Retractable confidential information in developing the OMI retractable syringe, and by inducing Double Dove and its affiliates to breach Double Dove's contract with Retractable by manufacturing retractable syringes for another company, namely OMI, all in violation of the statutory and common laws of the State of Texas.

49. Defendant's actions have caused injury and economic loss to Retractable in an amount greatly in excess of the minimum jurisdictional limits of this Court.

Count V – Unfair Competition and False Advertising

50. The preceding paragraphs of this Complaint are incorporated herein by reference as if fully set forth.

51. The foregoing actions of OMI, done intentionally and with full knowledge of their falsity and in reckless disregard of the rights of Retractable, in promoting the sale of OMI's accused products in the United States, constitute unfair competition, wrongful disparagement and false advertising in violation of 15 U.S.C. 1125(a), and have caused damage and loss of sales and profits to Retractable and its shareholders.

VII. PRAYER

WHEREFORE, premises considered, Retractable seeks judgment and relief against Defendant, including:

(a) OMI be adjudged and decreed to have directly, indirectly, and/or contributorily infringed the '584 and '224 patents;

(b) OMI be adjudged and decreed to have willfully and deliberately infringed the '584 and '224 patents;

(c) OMI be ordered to pay actual damages to Retractable and Shaw, but not less than a reasonable royalty, by reason of OMI's infringement of the '584 and '224 patents together with prejudgment interest, costs and increased damages pursuant to 35 U.S.C. § 284;

(d) A permanent injunction be entered against OMI, and its officers, agents, servants and employees, and all entities and individuals acting in concert with them, to permanently restrain any further infringement of the '584 and '224 patents and from making false claims regarding the products of OMI or Retractable;

(e) This case be declared an "exceptional case" within the meaning of 35 U.S.C. §285 and reasonable attorneys' fees, costs and treble damages be awarded to Plaintiffs;

(f) Entry of judgment against the Defendants on the above claims;

(g) Damages in an amount otherwise sufficient to compensate Retractable for its loss;

(h) Entry of judgment that this is an exceptional case and awarding Retractable its costs, expenses, and reasonable attorney fees for prosecuting this action against Defendants;

(i) Entry of preliminary and permanent injunctions enjoining the Defendants from disclosing or using any confidential information or trade secrets of Retractable or from selling retractable syringes that incorporate any confidential information or trade secrets of Retractable;

(j) Entry of judgment for pre-judgment interest and post-judgment interest; and

(k) Such other and further relief to which Retractable may be justly entitled.

VIII. JURY DEMAND

Retractable demands a trial by jury as their right under the Seventh Amendment to the Constitution of the United States or as given by statute. Fed. R. Civ. P. 38.

Dated this 1st day of April, 2008

Respectfully submitted,

/s/ Roy W. Hardin

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